

3529. Adulteration and misbranding of conjugated estrogens. U. S. v. 5 Bottles * * *. (F. D. C. No. 30949. Sample No. 6874-L.)

LIBEL FILED: May 8, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about April 9, 1951, from Pittsburgh, Pa. This was a return shipment.

PRODUCT: 5 1,000-tablet bottles of *conjugated estrogens* at New York, N. Y. Examination showed that the total amount of estrogens actually present per tablet calculated to 0.69 mg., expressed as a mixture of sodium estrone sulfate and sodium equilin sulfate.

LABEL, IN PART: "Tablets Water Soluble Conjugated Estrogens * * * Robin Pharmacal Corp. New York, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mgm. of estrogens in their water-soluble form, expressed as sodium estrone sulfate and sodium equilin sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 Mgm. of estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate and sodium equilin sulfate" was false and misleading as applied to an article which contained a total amount of estrogens per tablet which calculated to 0.69 milligrams of a mixture of sodium estrone sulfate and sodium equilin sulfate.

DISPOSITION: July 31, 1951. The libel proceedings in the instant case having been removed to the Eastern District of New York and having been consolidated with two other cases relating to the same product, and International Hormones, Inc., Brooklyn, N. Y., claimant, having consented to the entry of a consolidated decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling of the containers, crushing of the tablets, and extraction of the hormones, with subsequent relabeling to insure compliance with the law.

3530. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Bottle * * *. (F. D. C. No. 30769. Sample No. 23102-L.)

LIBEL FILED: March 13, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about December 29, 1950, by Success Chemical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 1 1,000-tablet bottle of *conjugated estrogens* at Bloomfield, N. J. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.74 mg. of sodium estrone sulfate per tablet.

RESULTS OF INVESTIGATION: According to the consignee, the bottle of *conjugated estrogens* was damaged when received, and the product was transferred by him to another bottle labeled "Premarin Tablets."

LABEL, IN PART: (Bottle, when shipped) "Tablets Conjugens (Conjugated Estrogens) 1.25 mg. Distributed by Success Chemical Co., Inc., Brooklyn, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the statement which appeared on the bottle label when shipped, namely, "Each tablet contains 1.25 mgm. of Estrogens in

their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained less than the stated amount of estrogens.

DISPOSITION: July 11, 1951. Default decree of condemnation and destruction.

3531. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Bottle, etc. (and 1 other seizure action). (F. D. C. Nos. 30926, 30927. Sample Nos. 24518-L, 24519-L.)

LIBEL FILED: April 17 and 19, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about February 5 and March 5, 1951, by Steroid Laboratories, Ltd., from Montreal, Canada, to Brooklyn, N. Y. A portion of the product had been relabeled by the Brooklyn consignee and had been shipped from Brooklyn, N. Y., to New York, N. Y.

PRODUCT: *Conjugated estrogens.* 2 tins, each containing 2 kilograms, at Brooklyn, N. Y.; and 1 tin containing 2 kilograms and 1 bottle containing 1,150 grams at New York, N. Y. Examination showed that the article contained not more than 20 milligrams of total estrogens per gram.

LABEL, IN PART: (Tin, when shipped from Canada) "Conjugated Estrogens (Equine) Powder. Each gram contains 27.8 mg. estrogens"; (tin and bottle, relabeled portion) "Conjugated Water Soluble Estrogens. Each gram contains 27.8 mg. estrogens."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 27.8 mg. estrogens per gram.

Misbranding, Section 502 (a), the label statement "Each gram contains 27.8 mg. estrogens as determined by Squibb modification of Kober Test" was misleading as applied to an article which contained not more than 20 mg. of total estrogens per gram.

The portion of the product at New York, N. Y., was adulterated and misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: July 31, 1951. The libel proceedings in the New York case having been removed to the Eastern District of New York and consolidated with the Brooklyn case and another case involving another lot of the same product, and International Hormones, Inc., Brooklyn, N. Y., having consented to the entry of a consolidated decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling of the containers, crushing of the tablets, and extraction of the hormones, with subsequent relabeling to insure compliance with the law.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE *

3532. Misbranding of Alcorine No. 28, Barrab No. 26, and Regene No. 29. U. S. v. Jerome Barnes (Barnes Co.). Plea of guilty. Fine of \$150 and probation for 1 year. (F. D. C. No. 30565. Sample Nos. 60495-K, 75607-K, 77320-K.)

INFORMATION FILED: June 11, 1951, Eastern District of Virginia, against Jerome Barnes, trading as the Barnes Co., Portsmouth, Va.

*See also Nos. 3521, 3524, 3526-3531.